**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Application of: | |
| John Nash et al. | |
| Serial No. | Art Unit: |
| Filed: concurrently herewith | Examiner: |
| For: FACE MASKS | Atty Docket: 0119/0029 |

**SUBMISSION OF PRIORITY DOCUMENT**

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto please find a certified copy of applicants' UK patent application No. 0300875.2 filed January 15, 2003.

Applicants request the benefit of said January 15, 2003 filing date for priority purposes pursuant to the provisions of 35 USC 119.

Respectfully submitted,

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Date: Jan 2 2004

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

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Signed

Dated 9 December 2003

**Patents Form 1/77**

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1/77

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*(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)*

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1. Your reference

0300020

15JAN03 E777146-1 C26047
P01/7700 0.00-0300875.2

2. Patent application number
*(The Patent Office will fill in this part)*

0300875.2

15 JAN 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

SMITHS GROUP PLC
765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)*

8032410001

If the applicant is a corporate body, give the country/state of its incorporation

GB

0546135 2001

4. Title of the invention

FACE MASKS

5. Name of your agent *(if you have one)*

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)*

1063304001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

| Country | Priority application number *(if you know it)* | Date of filing *(day / month / year)* |
|---|---|---|

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

| Number of earlier application | Date of filing *(day / month / year)* |
|---|---|

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

*a) any applicant named in part 3 is not an inventor, or*
*b) there is an inventor who is not named as an applicant, or*
*c) any named applicant is a corporate body.*
*See note (d))*

YES

**Patents Form 1/77**

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

| | |
|---|---|
| Continuation sheets of this form | |
| Description | 9 |
| Claim(s) | |
| Abstract | |
| Drawing(s) | 4 + 4 |

10. If you are also filing any of the following, state how many against each item.

| | |
|---|---|
| Priority documents | |
| Translations of priority documents | |
| Statement of inventorship and right to grant of a patent *(Patents Form 7/77)* | |
| Request for preliminary examination and search *(Patents Form 9/77)* | |
| Request for substantive examination *(Patents Form 10/77)* | |
| Any other documents *(please specify)* | |

11. I/We request the grant of a patent on the basis of this application.

Signature J Flint Date 14 JAN 2003

12. Name and daytime telephone number of person to contact in the United Kingdom J.M. FLINT 020 8457 8220

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# FACE MASKS

This invention relates to face masks.

Face masks are used to supply gas to a patient for various purposes and are designed to seal with the skin surface around the nose and mouth. There are many different forms of face mask currently available but often these suffer from disadvantages such as large bulk, weight, discomfort in use or poor sealing.

It is an object of the present invention to provide an alternative face mask.

According to one aspect of the present invention there is provided a face mask of a plastics material comprising a relatively soft canopy member having a peripheral sealing edge providing a seal with the skin around the nose and mouth of a patient, the canopy member being moulded as one shot in a dual-shot moulding process, and a relatively rigid reinforcement member moulded integrally with the canopy member as another shot in the dual-shot moulding process.

According to another aspect of the present invention there is provided a method of making a face mask comprising the steps of moulding a first component in a mould from a relatively high temperature plastics material and subsequently moulding a second component from a relatively low temperature plastics material directly on the first component while the first component is in the mould.

According to a third aspect of the present invention there is provided a face mask having a canopy shaped to extend around the mouth and nose of a patient, the canopy having a peripheral sealing edge arranged to seal with the patient's skin around the nose and mouth, the peripheral sealing edge being tapered to a reduced thickness and increased flexibility at its edge.

According to a fourth aspect of the present invention there is provided a face mask shaped to extend around the nose and mouth of a patient, the mask having a gas connector projecting therefrom for connection to a gas supply tube, the connector being located in line with the mouth of the patient and being angled such that it projects down when the mask is applied to the patient's face in an upright position.

According to a fifth aspect of the present invention there is provided a face mask shaped to extend around the nose and mouth of a patient, the mask having a gas port for connection to a supply of breathing gas and a valve separate from the port, the valve being arranged to allow air to flow into the mask when there is inadequate supply of breathing gas at the gas port.

According to a sixth aspect of the present invention there is provided a face mask shaped to extend around the nose and mouth of a patient, the mask having a gas port for connection to a supply of breathing gas and selectively closable vent means arranged to allow gas to flow out of the mask.

The vent means preferably includes a cap member that is movable between two discrete positions where the vent is open or the vent is closed.

A face mask according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

| | |
|---|---|
| Figure 1 | is a front view of the mask; |
| Figure 2 | is a side elevation view of the mask on the face of a patient; |
| Figure 3 | is a sectional side elevation view of the mask; |
| Figures 4 and 5 | are sectional side elevation views of a part of the mask to an enlarged scale indicating how it seals on the face; |
| Figure 6 | is a perspective view of a controlled leak device; |
| Figure 7 | is a sectional side elevation view of an anti-asphyxia valve; |
| Figure 8 | shows two straps used in the mask harness; |
| Figure 9 | is a side elevation view of the mask showing an alternative harness; |

Figure 10 is an elevation view of the edge of the mask showing a tube access; and

Figure 11 is a sectional view of the tube access of Figure 10.

With reference first to Figures 1 to 5, the mask comprises two parts, namely a canopy 1 and a support frame 2. The canopy 1 is moulded of a relatively soft, flexible plastics material, such as, SEBS styrene ethylene butadiene styrene with a Shore hardness of about ...., whereas the support frame 2 is moulded of a harder material, such as a polypropylene copolymer with a Shore hardness of about ..... The canopy 1 and support frame 2 are moulded integrally with one another by a dual-shot moulding process in which the higher temperature plastics material forming the frame 2 is moulded first in a mould cavity, then the mould is enlarged to form a cavity for the canopy, which is subsequently moulded from a lower temperature plastics material. This results in the canopy and support frame being integrally bonded together.

The canopy 1 is of generally triangular shape with a peripheral edge 10 shaped to extend under the mouth, up the cheeks, along the sides and across the nose. The canopy 1 has a domed internal cavity 11 in which the nose is received. The edge 10 is curved inwardly into the cavity in a C shape so that, when the mask is placed against the face, as shown in Figures 4 and 5, a curved contact region 12 contacts the skin with the lip 13 being on or spaced slightly above the skin. The canopy 1 varies in thickness from about 2mm across most of its surface tapering to about 1.5mm in the contact region 12 and to about 0.7mm at the lip 13.

This makes the edge 10 very flexible. The seal with the patient's skin could be further enhanced by an adhesive material on the contact region.

The frame member 2 has a generally star shape with three radially-extending arms 20, 21 and 22. One arm 20 projects down and is formed with a gas connector port 23 positioned in line with the patient's mouth and angled downwardly at an angle of about 20° to the horizontal when mounted on the patient's face in an upright position. A second arm 21 projects upwardly to the left, as viewed in Figure 1, and includes a controlled leak device 30 to be described in greater detail later. The second arm 21 is terminated by a lateral bar 24 extending parallel to the edge of the mask in the region of the patient's right cheek. The third arm 22 projects upwardly towards the right and includes an anti-asphyxia valve 25 as described in greater detail later. The third arm is terminated by a lateral bar 26 extending parallel to the edge of the mask in the region of the patient's left cheek.

Moulding the face mask in a dual-shot process gives various advantages. It enables the mask to made very thin and light in weight with a very flexible seal whilst having sufficient rigidity across its central portion to support the connector and the various other components without deformation. Because the mask can be made thin, the upper part of the mask can be shaped to follow closely the profile of the nose. This reduces interference to the patient's eyesight and can make the mask less claustrophobic than some previous masks. The dual-shot process also enables the mask to be made with high transparency so that the part of the face enclosed by the mask can be seen clearly by the clinician.

The controlled leak device 30 is shown most clearly in Figures 6 and 7 and is formed of two components, namely a base 31 and a cap 32. The base 31 comprises a circular plate 33 secured in an aperture in the frame 2. The plate 33 has three gas passages 34 extending through it and a central stem 35 projecting from the external surface. The stem 35 is hollow and cylindrical with a male luer slip surface to receive a female connector. The stem 35 also has key formations 36 on its outer surface. The cap 32 has a plate 37 of the same diameter as the base plate 33 and with three openings 38 spaced in the same manner as the passages 34. A hollow sleeve 39 projects from the centre of the plate 33. The sleeve 39 is shaped to fit on the stem 35 and has keyway formations on its inner surface (not shown). The key and keyway formations are arranged to prevent rotation of the cap 32 on the base 31 and to ensure that the cap can only be fitted on the base either with the openings 38 aligned with the gas passages 34 or with them not aligned and thereby preventing flow of gas. When the cap 32 is mounted on the base with the openings 38 aligned with the gas passages this permits a small flow of gas through the leak device. This is sufficient to allow air exhaled by the patient to flow out through the leak without enabling pressure of gas supplied to the mask to fall below the level needed for CPAP ventilation. When the cap 32 is removed, a tube (not shown) can be connected to the tapered stem 35 for carbon dioxide sampling purposes.

The anti-asphyxia valve 25 is shown in Figure 7 and includes a rigid plate 70, which is flat on its upper, outer surface 71 and has a concave, domed recess 72 on its lower, inner surface. Four holes 73 extend through the plate 70 between the recess 72 and the outer surface 71 and are equally distributed around the edge of the recess. A narrow ledge 74 extends around the outside of the recess 72. The valve 25 also includes a flexible, resilient diaphragm 75 providing a valve member for the valve. The diaphragm 75 has a peripheral

ledge 76 that is clamped on the ledge 74 by a ring (not shown), and a domed central portion 77 with a central aperture 78. The radius of curvature of the domed portion 77 in its natural state is greater than that of the recess 72 so that it is spaced away from the recess and allows free flow of gas through the aperture 78 and holes 73. When the internal pressure within the mask is raised, the domed portion 77 is forced outwardly, that is, upwardly into contact with the recess 72, thereby sealing the holes 73 closed. The valve 25, therefore, closes when there is high gas pressure within the mask but opens when gas pressure drops to permit the patient to breath atmospheric air in through the valve. Other, conventional forms of valve could be used to allow the patient to inhale via the valve should there be an obstruction to gas flow to the inlet port 23. Previous anti-asphyxia valves have been incorporated into the gas inlet port connection but this has the disadvantage of increasing the bulk at the inlet and thereby increasing the bending moment exerted on the mask by the associated inlet tubing.

Attached to both the lateral bars 24 and 26 is a strip 27 and 28 of a hook fastening material, such as of the kind sold under the Velcro trade mark (Velcro is a Registered Trade Mark of Velcro BV), which is used to secure an end of a harness 40. The harness 40 comprises two flexible, elastic straps 41 and 42, as shown in Figure 8, which both have a pad 43 and 44 of a loop fastening material at one end so that they can be secured with the strips 27 and 28 on the mask frame 2. At their other ends, one straps 41 has a pad 45 of a hook material and the other strap 42 has a pad 46 of a loop material. Opposite ends of the straps 41 and 42 are enlarged laterally to accommodate the pads 43 to 46. In this way, the straps 41 and 42 can be secured with one another at one end at the back of the patient's head and can be secured at their other ends with the mask frame 2. The arrangement allows for the straps to be

secured to the frame and to one another at any angle, thereby allowing flexibility in positioning of the harness so as to accommodate a variety of patients.

An alternative harness arrangement 140 is illustrated in Figure 9. This harness 140 has two straps 141, only one of which is shown, which are fastened together at the back of the head by hook and loop fastening material (not shown). The straps 141 are fastened to the mask itself by means of two posts 142 and 143 projecting from the side of the mask and spaced one above the other, which extend through apertures 142' and 143' in the straps. The forward end of the straps 141 is of triangular shape having a lateral portion 144 extending upwardly at an angle of about 90° to the main part of the strap, and rearwardly-extending portion 145 extending rearwardly and downwardly at an angle of about 45° to the upper end of the lateral portion. The rearwardly-extending portion 145 has a free rear end to which is attached a pad 146 of a hook or loop material, which attaches to a cooperating pad 147 on the main part of the strap. This arrangement enables the pressure exerted by the mask on the face to be adjusted to alter its distribution. Pressure exerted by the upper part of the mask can be increased or reduced by appropriately moving the end of the portion 145 to attach it to a part of the pad 147 that is further back or further forwards. The straps each have a quick-release tab 148 in the region of the upper aperture 142'. One or both of these tabs 148 can be pulled down to release the harness 141 from the mask.

Various modifications are possible to the mask. The edge seal of the mask may be modified to allow a nasogastric tube 90 to pass through the edge 10, as shown in Figures 10 and 11. In this arrangement the edge of the mask is moulded with a keyhole-shape formation 91 of reduced thickness, which can be easily torn or cut. The keyhole-shape formation 91 has

a very narrow entrance portion slit 92 extending to the edge, and a circular sleeve portion 93 located above it and projecting a short distance inwardly. When used without a nasogastric tube, this formation is left in place so that there is no path for gas leakage in this region. When a nasogastric tube is to be used, the keyhole-shape formation is torn or cut to form a keyhole-shape aperture so that the tube 90 can be pushed sideways in through the narrow part of the aperture, which may be self-closing, and located in the circular, sleeve part of the aperture where it is a close, sealing fit. If the mask needs to be removed at any time, the tube can be easily peeled out of the aperture so that its patient end can be left in place in the patient and its machine need not be disconnected from any apparatus to which it is connected. The mask can be subsequently replaced on the patient after having pushed the nasogastric tube into the aperture.

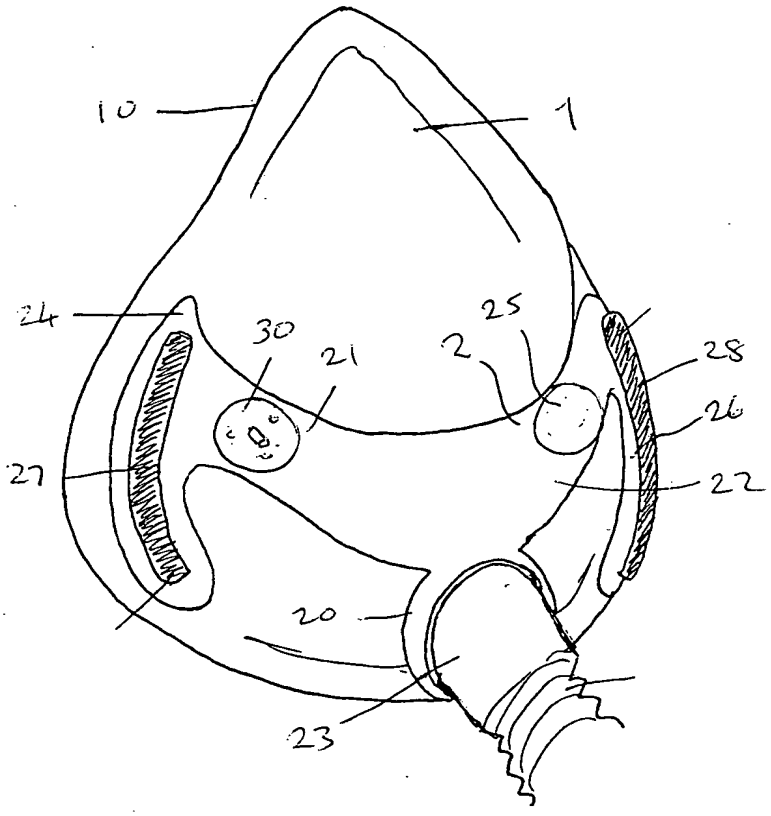


FIG. 1

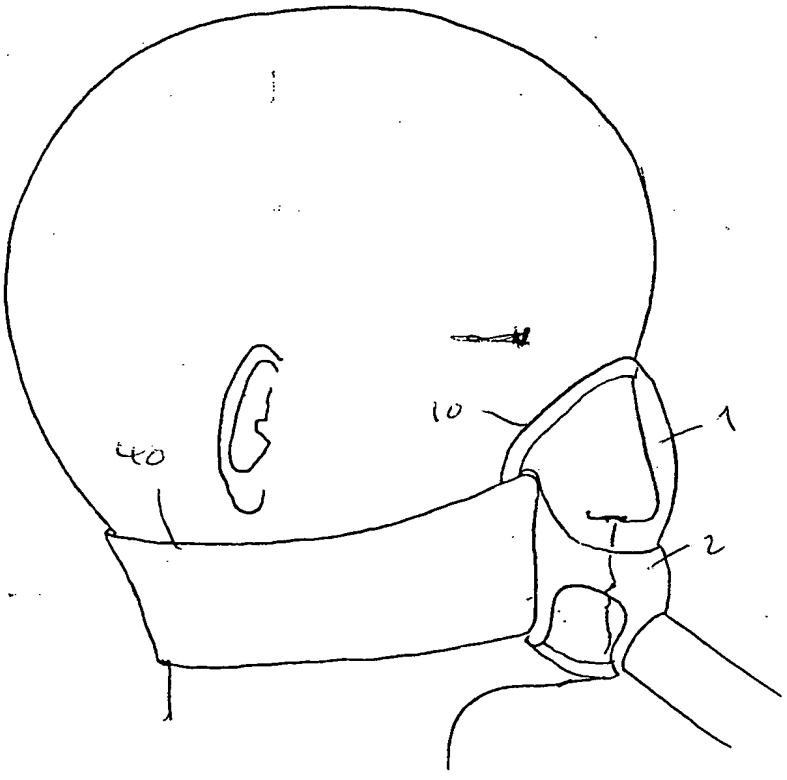


FIG 2

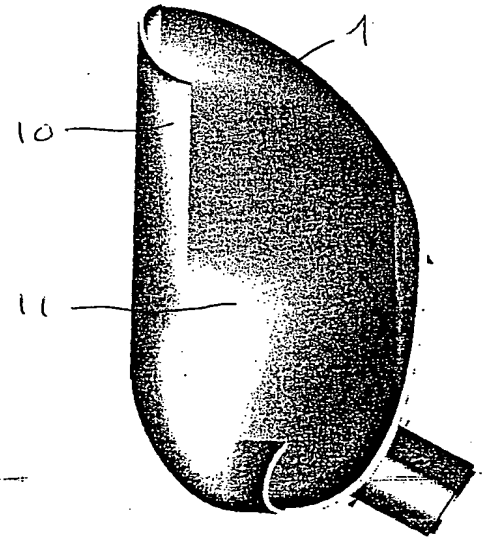


FIG. 3

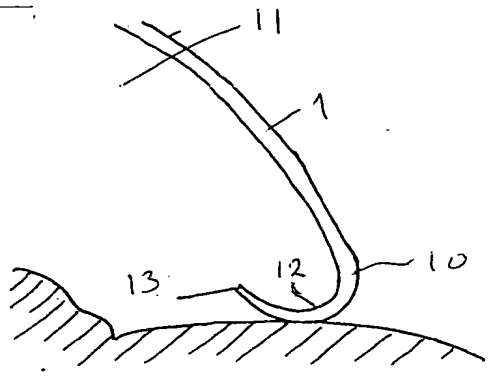


FIG 4

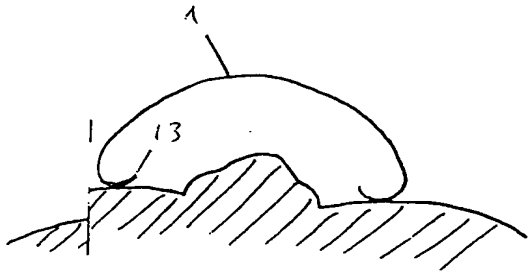


FIG. 5

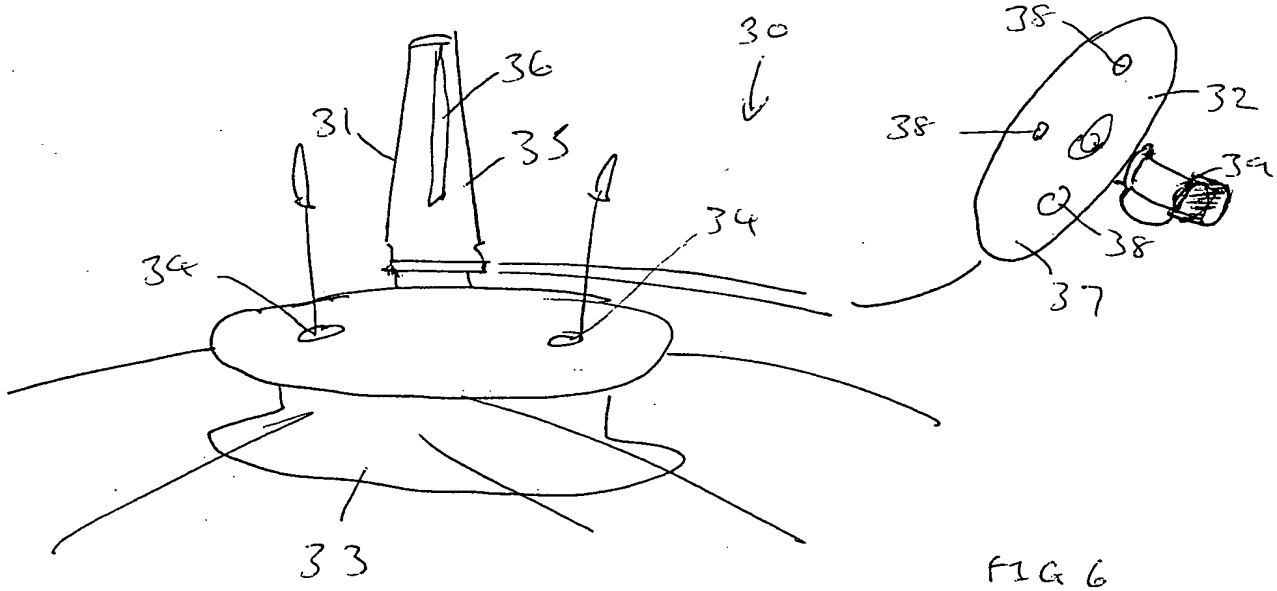


FIG 6

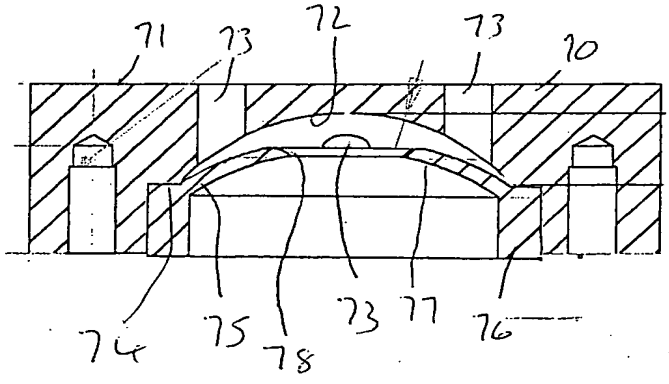


FIG. 7

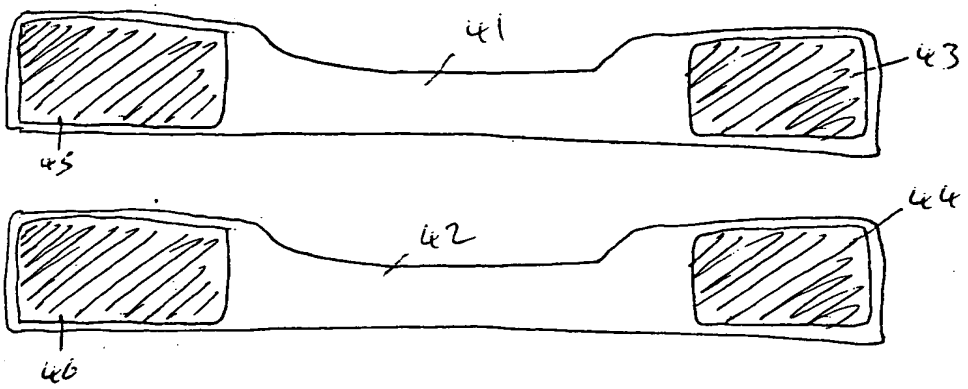


FIG. 8

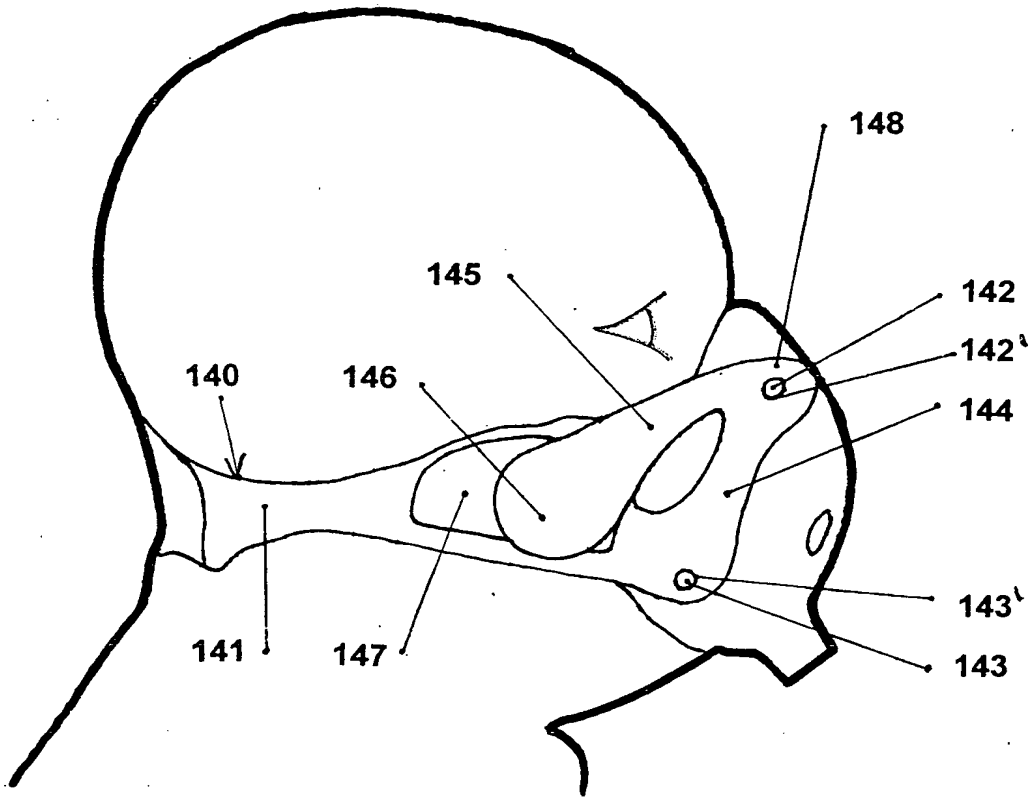


FIG. 9

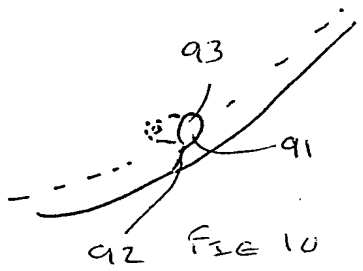


FIG 10

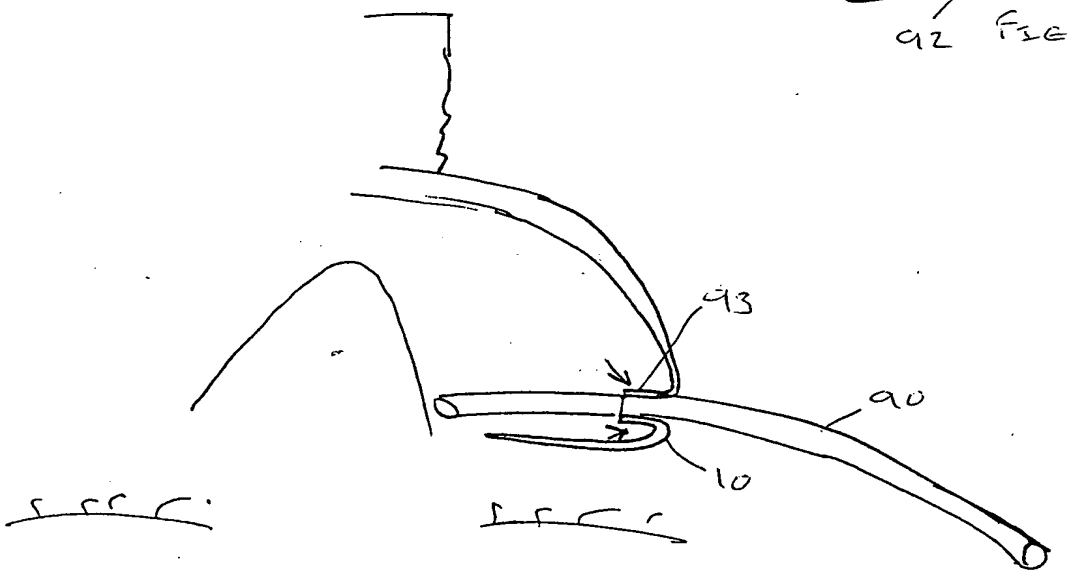


FIG. 11